STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
FACILITY LICENSING AND INVESTIGATIONS SECTION

IN RE: Center for Advanced Reproductive Services, PC
d/b/a Center for Advanced Reproductive Services
263 Farmington Avenue
Farmington, CT 06030

CONSENT ORDER

WHEREAS, Center for Advanced Reproductive Services, PC (hereinafter the "Licensee"), has been issued License No. 0319 to operate an Outpatient Surgical Center known as Center for Advanced Reproductive Services (hereinafter the "Facility") under Connecticut General Statutes 19a-490 by the Department of Public Health, State of Connecticut (hereinafter the "Department"); and

WHEREAS, on or about April 22, 2009, pursuant to the requirements contained in Conn. Gen. Stat. § 19a-127n, the Facility reported to the Department an adverse event which occurred at the Facility on or about April 15, 2009.

WHEREAS, the Facility Licensing and Investigations Section (hereinafter "FLIS") of the Department conducted unannounced inspections on May 1 and 21, 2009; and

WHEREAS, the Department, during the course of the aforementioned inspections identified violations of the Connecticut General Statutes and/or Regulations of Connecticut State Agencies in a violation letter dated June 16, 2009 (Exhibit A – copy attached); and

WHEREAS, the Department recognizes the measures taken by the Licensee to address certain violations identified in the violation letter of June 16, 2009, as more fully set forth in the Licensee's revised corrective action plan dated September 15, 2009; and

WHEREAS, without admitting wrongdoing or fault, the Licensee is willing to enter into this Consent Order and agrees to the conditions set forth herein.

NOW THEREFORE, the FLIS of the Department acting herein and through Barbara Cass, Public Health Services Manager, and the Licensee, acting herein and through Claudio Benadiva, M.D., its President, hereby stipulate and agree as follows:

1. The Licensee, having contracted with an Independent In Vitro Fertilization (IVF) Laboratory Consultant to review the facilities laboratory policies and procedures, shall within twenty-one (21) days of the execution of this Consent Order, submit to the Department a copy of the curriculum vitae of the consultant, if the facility has not already done so. In addition, the facility shall, share with the Department the report of the Independent In Vitro Fertilization Laboratory Consultant and, shall engage the services of the same consultant to evaluate the progress of the facility in implementing recommendations made as a result of the initial onsite review.
2. Within three (3) months of the execution of this Consent Order, the IVF Laboratory Consultant shall re-evaluate the Licensee. The re-evaluation shall determine the Licensee's ability to implement and maintain quality care and services. Upon conclusion of said review, the Independent IVF Laboratory Consultant shall provide the Department with a comprehensive report of the assessment and any remedial recommendations made by the Independent IVF Laboratory Consultant.
3. The Department shall have the final determination, which shall be binding upon the Licensee to accept or reject the Independent IVF Laboratory Consultant recommendations should the parties be unable to reach a mutual agreement.
4. The Licensee's Administrator and the Nurse Manager shall meet with the Department every six (6) weeks for the first six (6) months after the effective date of this Consent Order and thereafter at quarterly intervals throughout the first year of this Consent Order. The meetings shall include discussions of issues related to the care and services provided by the Licensee and the Licensee's compliance with applicable state statutes and regulations.
5. Any records maintained in accordance with any state or federal law or regulation or as required by this Consent Order shall be made available to the Department upon request.
6. Within thirty (30) days of the execution of this Consent Order, if not already completed, the Licensee shall:

a. Review, revise and/or develop as necessary policies and procedures regarding the securing of frozen embryos from the cryo-preservation bank and the verification process prior to and at the time of embryo transfer; and

b. Ensure all staff are inserviced to the policies and procedures as required in Paragraph 6a.

7. Within ninety (90) days of the execution of this Consent Order, the Licensee shall establish a mechanism, whereby the Licensee's Quality Assurance Program (QAP), on an ongoing basis, reviews and evaluates the following:

   a. Compliance with facility policies regarding the security of frozen embryos from the cryo-preservation bank;

   b. Verification process to and at the time of embryo-transfer; and

   c. Implementation and compliance with the Independent IVF Laboratory Consultants recommendations.

8. Minutes of the QAP minutes shall be kept for a minimum of three (3) years and made available for review upon request of the Department.

9. The Licensee, within seven (7) days of the execution of this document, shall designate an individual within the Facility to monitor the requirements of this Consent Order. The name of the designated individual shall be provided to the Department. Said individual assigned this responsibility shall submit reports every six (6) weeks for the first six (6) months than quarterly for the period of this Consent Order.

10. In accordance with Connecticut General Statute Sections 19a-494 (4) and 19a-494 (7) the Commissioner of the Department of Public Health hereby issues a reprimand to the Licensee to comply with all statutory and regulatory requirements pertaining to the operation of an Outpatient Surgical Center.

11. The Licensee shall pay a monetary penalty to the Department in the amount of three thousand dollars ($3,000.00), by money order or bank check payable to the Treasurer of the State of Connecticut and mailed to the Department within two (2) weeks of the effective date of this Consent Order. The money penalty shall be directed to:

Donna Ortelle, R.N., M.S.N., Supervising Nurse Consultant
Facility Licensing and Investigations Section
Department of Public Health
410 Capitol Avenue, MS #12 FLIS
P.O. Box 340308
Hartford, CT 06134-0308

12. All parties agree that this Consent Order is an agreement with the Department with all of the rights and obligations pertaining thereto and attendant thereon. Nothing herein shall be construed as limiting the Department's available legal remedies against the Licensee for violations of this Consent Order or of any other statutory or regulatory requirements, which may be sought in lieu of or in addition to the methods of relief listed above, or any other administrative and judicial relief provided by law. This Consent Order may be admitted by the Department as evidence in any proceeding between the Department and the Licensee in which compliance with its terms is at issue. The Licensee retains all of its rights under applicable law.
13. The execution of this document has no bearing on any criminal liability without the written consent of the Director of the Connecticut Medicaid Fraud Control Unit or the Bureau Chief of the Department of Criminal Justice's Statewide Prosecution Bureau.
14. The terms of this Consent Order shall remain in effect for a period of two (2) years from the effective date of this document unless otherwise specified in this document.
15. The Licensee understands that this Consent Order and the terms set forth herein are not subject to reconsideration, collateral attack or judicial review under any form or in any forum including any right to review under the Uniform Administrative Procedure Act, Chapter 368a of the Statutes, Regulations that exists at the time the agreement is executed or may become available in the future, provided that this stipulation shall not deprive the Licensee of any other rights that it may have under the laws of the State of Connecticut or of the United States.
16. Should the licensee not be able to maintain substantial compliance with the requirements of this consent order, the Department retains the right to issue charges including those identified in the violation letter dated June 16, 2009 referenced in this document.
17. The Licensee consulted with its attorney prior to the execution of this Consent Order.

WITNESS WHEREOF, the parties hereto have caused this Consent Order to be executed by their respective officers and officials, which Consent Order is to be effective as of the later of the two dates noted below.

CENTER FOR ADVANCED REPRODUCTIVE SERVICES, P.C. - LICENSEE

By: _____
Claudio Benadiva, M.D., President

On this 8th day of June, 2010, personally appeared Claudio Benadiva and made oath to the truth of the statements contained herein.

My Commission Expires: 5/31/2015
(If Notary Public)

_____
Notary Public
Commissioner of the Superior Court

STATE OF CONNECTICUT,
DEPARTMENT OF PUBLIC HEALTH

6-22-10
Date

By: _____
Barbara Cass, R.N.,
Public Health Services Manager
Facility Licensing and Investigations Section

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

June 16, 2009

Paul Verrastro, Administrator
Center For Advanced Reproductive Services
263 Farmington Avenue
Farmington, CT 06030

Dear Mr. Verrastro:

Unannounced visits were made to the Center For Advanced Reproductive Services on May 1 and 21, 2009 by a representative of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting an investigation with additional information received through June 11, 2009.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

An office conference has been scheduled for Tuesday July 7, 2009 at 1:30 PM in the Facility Licensing and Investigations Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut. Should you wish legal representation, please feel free to have an attorney accompany you to this meeting.

Please prepare a written Plan of Correction for the above mentioned violations to be presented at this conference.

Each violation must be addressed with a prospective Plan of Correction which includes the following components:

- Measures to prevent the recurrence of the identified violation, (e.g., policy/procedure, inservice program, repairs, etc.).
- Date corrective measure will be effected.
- Identify the staff member, by title, who has been designated the responsibility for monitoring the individual plan of correction submitted for each violation.

If there are any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Ann Marie Montemerlo, RN
Supervising Nurse Consultant
Facility Licensing and Investigations Section

amm:sn

c. Director of Nurses
Medical Dirctor
President
Investigation #CT 9480

Phone: (860) 509-7400
Telephone Device for the Deaf (860) 509-7191
410 Capitol Avenue - MS # 12HSR
P.O. Box 340308 Hartford, CT 06134
An Equal Opportunity Employer

DATE(S) OF VISIT: May 1 and 21, 2009

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

The following are violations of the General Statutes of Connecticut Section 19a-127o and/or the Regulations of Connecticut State Agencies Section 19-13-D56 (c) Ownership and Administration (1) and/or (d) Chief Executive Officer (3) and/or (i) General (5) and General Statute of Connecticut 19a-127o.

1. Based on clinical record reviews, review of facility policies and interviews with staff, the facility failed to ensure that the embryo implanted into Patient #1, belonged to the patient. The findings include:

a. Patient #1 was admitted to the treatment facility on 4/14/09 to undergo a surgical transfer of two (2) blast cells (embryos) that were the biological product of Patient #1 and the patient's partner. Patient #1's blast cells had been in cryostorage at the facility. On 4/14/09, Patient #1 was admitted to the facility, a blast transfer was completed and the patient was discharged. On 4/15/09, a staff member at the treatment facility identified that the blast cells transferred into Patient #1 belonged to Patient #2. Patient #1 was notified of the error on 4/15/09. Patient #1 agreed to terminate any pregnancy that may have occurred as a result of the blast transfer and initiated treatment. Interview with the VP of Operations on 6/11/09 at 10:05 AM identified that as of 5/22/09, Patient #1 was not pregnant.

Interviews with staff on 5/1/09 and 5/21/09 identified that Patient #1 and Patient #2 had the same last names. The treatment facility used cryocards to identify where a patient's blast cells were located in the cryostorage area. On 4/14/09, Embryology Technologist #1 mistakenly used Patient #2's cryocard, removed Patient #2's blast cells from cryostorage, and prepared Patient #2's blast cells for a transfer into Patient #1. Embryology Technologist #1 failed to follow facility policies that directed staff to identify a patient and blast cells using the patient's name, last four digits of the patient's social security number, and the patient's medical record number. Once Patient #2's blast cells were removed from the cryovial, all specimen plates and paper work identified the blast cells as belonging to Patient #1.

2. Based on review of facility documentation and staff interviews, the facility failed to belong to a Patient Safety Organization. The findings include:

a. Interviews with the VP of Operations on 5/21/09 at 11:10 AM and 6/11/09 at 10:05 AM identified that although the facility belonged to the College of American Pathologists and the American Association of Ambulatory Health Care, both entities having quality improvement requirements, the facility was not a member of a specific Patient Safety Organization as per the General Statutes of Connecticut.